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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,518	03/01/2007	Jacques Marie Rene Jan Huyghe	4017/1US	3507

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EXAMINER	
YANG, ANDREW	
ART UNIT	PAPER NUMBER
3775	

NOTIFICATION DATE	DELIVERY MODE
06/15/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/564,518	HUYGHE ET AL.	
	Examiner	Art Unit	
	ANDREW YANG	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,21-27,29-33 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,21-27,29-33 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 3, 2011 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11, 21, 24-27, and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al. (U.S. Patent No. 5458643) in view of Coury et al. (U.S. Patent No. 7008635), Stoy (U.S. Patent No. 6264695) and further in view of Stubstad et al. (U.S. Patent No. 3867728).

Oka et al. discloses a prosthesis having a flexible portion 22 and at least one less flexible portion 4. The flexible portion is formed of a hydrogel. The less flexible portion can be provided on the upper/lower/inner sides of the flexible portion (Figures 3a-3e)

and serves as an endplate. The hydrogel 22 is PVA and has swelling characteristics comparable to those of a natural disc. The device is intended to be implanted in a human or animal (Figure 4).

Oka et al. fails to disclose the hydrogel containing chopped fibers. Coury et al. teaches using hydrogels to form intervertebral disc implants and that fibers can be added to the hydrogel to improve their toughness under load and shear (Column 9, Lines 48-51). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Oka et al. with the hydrogel containing fibers in view of Coury et al. to improve the toughness of the hydrogel under load and shear and to maintain biocompatibility and lubricity.

Oka et al, and Coury et al. also fail to disclose the hydrogel having negatively charged groups. Stoy teaches a spinal disc implant formed of a hydrogel (column 8, LInes 17-19). The hydrogel contains negatively charged groups so that the device is highly biocompatible but also have a very low wet friction so as to not erode natural tissue (Column 14, Lines 2-7). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Oka et al. as modified by Coury et al., Stubstad et al. and Bao et al. with a hydrogel having negatively charged groups further in view of Stoy so that the device would be highly biocompatible and have a very low wet friction so as to not erode natural tissue.

Oka et al. also fails to disclose fibers wound around and encompassing the whole of the flexible portion and at least one less flexible portion. Stubstad teaches an implant having a flexible portion and at least one less flexible portion 11. The less

flexible portion and the flexible portion have a fiber 29 that is wound around and encompass the whole of the flexible portion and at least one flexible portion (Figure 1). The fiber 29 provides a means for securely anchoring the pieces together thereby having a low elasticity modulus. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Oka et al. with fibers wound around and encompassing the whole of the flexible portion and at least one less flexible portion in view of Stubstad to securely anchor the separate pieces together.

Regarding claims 8-10, it would have been obvious to one skilled in the art at the time the invention was made to construct the flexible portion of Oka et al. as modified by Coury et al. and Stubstad having the claimed thicknesses and the percentage of fibers, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 32 and 33, it would have been obvious to one skilled in the art at the time the invention was made to construct the device of Oka et al. as modified by Coury et al. and Stubstad et al. with fibers capable of absorbing hydrogel monomers or made of polyurethane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding claims 24-27, 29 and 30, it is noted that the Applicant is claiming an article of manufacture and not the process of forming/making the device, accordingly, the manner in which the device is formed, i.e. winding or knitting, slicing, is given little

weight as long as the final product is shown. The burden is upon the applicant to come forward with evidence establishing an unobvious difference between the prior art and the current application. In re Marosi, 218 USPQ 289 (Fed Cir. 1983). Furthermore, it can be seen that the fiber 29 of Stubstad is wound around the implant

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al. (U.S. Patent No. 5458643) in view of Coury et al. (U.S. Patent No. 7008635), Stubstad et al. (U.S. Patent No. 3867728) and further in view of Bao (U.S. Patent No. 5047055) and Stoy (U.S. Patent No. 6264695).

Oka et al, Coury et al. and Stubstad et al. disclose the claimed invention except for reducing the volume of the implant prior to insertion by soaking the implant in a salt bath. Bao et al. teaches a hydrogel implant for an intervertebral disc that is implanted in a human (Column 7, Lines 30-40). Prior to implanting the volume of the prosthesis is reduced by dehydration so as to reduce the size of the implant for insertion (Column 7, Lines 55-60). It would have been obvious to one skilled in the art at the time the invention was made to reduce the size of the device of Oka et al. as modified by Coury et al. and Stubstad et al. by dehydration prior to inserting further in view of Bao et al. in order to reduce the size of the implant for insertion.

Bao et al. fails to disclose dehydrating by immersing the implant in a hypertonic salt bath. Stoy teaches using a salt bath to reduce the volume of the prosthesis in order to not completely dehydrate the implant and avoiding making the implant brittle for insertion (Column 13, Lines 10-15). It would have been obvious to one skilled in the art at the time the invention was made to reduce the volume of the device of Oka et al. as

modified by Coury et al., Stubstad et al. and Bao et al. by using a salt bath further in view of Stoy in order to prevent the implant from becoming brittle for insertion.

Response to Arguments

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW YANG whose telephone number is (571)272-3472. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew Yang/
Examiner, Art Unit 3775